

SAFETY DATA SHEET



1. Identification

Names

Product name : Nurofen for Children 5-12 Years Suspension 4%
SDS no. : D0187533
Formulation # : 0094091 (Strawberry); 0093421 (Orange)
Supplier : AUSTRALIA
RECKITT BENCKISER (AUSTRALIA) PTY LIMITED
680 George St , Sydney, NSW 2000
Tel: +61 (02) 9857 2000

NEW ZEALAND
Reckitt Benckiser (New Zealand) Limited
2 Fred Thomas Drive, Takapuna,
Auckland, New Zealand 0622
Tel: +64 9 484 1400

Poison Information contact: : Australia - 13 11 26
New Zealand - 0800 764 766 or 0800 POISON

Uses

Product use : Self medication for pain relief.

2. Hazard identification

Classification of the substance or mixture : This is a cosmetic or a medicinal product under the ANZ cosmetic or pharmaceutical legislation and has undergone a safety assessment. Finished cosmetic and medicinal products are exempt in the ANZ from the legislation requiring the provision of a Safety Data Sheet (SDS). The purpose of this SDS is to provide information about the substances within this product to facilitate its safe use, transport, storage and disposal.

GHS label elements

Signal word : Not applicable.

Hazard statements : Not applicable.

Precautionary statements

Prevention : Not applicable.

Response : Not applicable.

Storage : Not applicable.

Disposal : Not applicable.

3. Composition/information on ingredients

Substance/mixture : Mixture

Ingredient name	% (w/w)	CAS number
Glycerol	≥10 - ≤30	56-81-5

3. Composition/information on ingredients

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified and hence require reporting in this section.

The total concentration of ingredients in this product, reported or not in this section, is 100%.

Occupational exposure limits, if available, are listed in Section 8.

4. First-aid measures

Description of necessary first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.
- Skin contact** : Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
- Ingestion** : Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed

Potential acute health effects

- Eye contact** : May cause eye irritation upon direct contact with eyes.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

Over-exposure signs/symptoms

- Eye contact** : No specific data.
- Inhalation** : No specific data.
- Skin contact** : No specific data.
- Ingestion** : No specific data.

Indication of immediate medical attention and special treatment needed, if necessary

- Notes to physician** : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
- Specific treatments** : No specific treatment.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training.

See toxicological information (Section 11)

5. Fire-fighting measures

Extinguishing media

- Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.
- Unsuitable extinguishing media** : None known.

Specific hazards arising from the chemical : No specific fire or explosion hazard.

- Hazardous thermal decomposition products** : No specific data.

5. Fire-fighting measures

- Special protective actions for fire-fighters** : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.
- Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.
- Hazchem code** : Not applicable

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Put on appropriate personal protective equipment.
- For emergency responders** : If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".
- Environmental precautions** : Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and material for containment and cleaning up

- Small spill** : Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.
- Large spill** : Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

See Section 1 for emergency contact information.

See Section 8 for information on appropriate personal protective equipment.

See Section 13 for additional waste treatment information.

7. Handling and storage

Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8).
- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.
- Conditions for safe storage, including any incompatibilities** : Do not store above the following temperature: 25°C (77°F). Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

8. Exposure controls/personal protection

Control parameters

Australia

Occupational exposure limits

Ingredient name	Exposure limits
Glycerol	Safe Work Australia (Australia, 12/2019). TWA: 10 mg/m ³ 8 hours.

New Zealand

Occupational exposure limits

Ingredient name	Exposure limits
glycerol	NZ HSWA 2015 - GRWM 2016 (New Zealand, 11/2020). WES-TWA: 10 mg/m ³ 8 hours. Form: Mist

- Appropriate engineering controls** : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.
- Environmental exposure controls** : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

Individual protection measures

- Hygiene measures** : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
- Eye/face protection** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.
- Skin protection**
- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.
- Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

9. Physical and chemical properties

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

Appearance

- Physical state** : Liquid.
- Colour** : Off-white.
- Odour** : Strawberry or Orange
- Odour threshold** : Not available.

9. Physical and chemical properties

pH	: 4 to 4.5
Melting point/freezing point	: Not available.
Boiling point, initial boiling point, and boiling range	: Not available.
Flash point	: Not available.
Evaporation rate	: Not available.
Flammability	: Not available.
Lower and upper explosion limit/flammability limit	: Not available.
Vapour pressure	: Not available.
Relative vapour density	: Not available.
Relative density	: 1.14 to 1.18
Solubility(ies)	:

Media	Result
cold water	Soluble
hot water	Soluble

Partition coefficient: n-octanol/water	: Not applicable.
Auto-ignition temperature	: Not available.
Decomposition temperature	: Not available.
Viscosity	: Not available.
<u>Particle characteristics</u>	
Median particle size	: Not applicable.

10. Stability and reactivity

Reactivity	: No specific test data related to reactivity available for this product or its ingredients.
Chemical stability	: The product is stable.
Possibility of hazardous reactions	: Under normal conditions of storage and use, hazardous reactions will not occur.
Conditions to avoid	: No specific data.
Incompatible materials	: No specific data.
Hazardous decomposition products	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Glycerol	LD50 Oral	Rat	12600 mg/kg	-

Conclusion/Summary No known significant effects or critical hazards.

Irritation/Corrosion

Not available.

Conclusion/Summary

Skin

No known significant effects or critical hazards.

11. Toxicological information

Respiratory No known significant effects or critical hazards.

Sensitisation

Not available.

Conclusion/Summary

Skin

No known significant effects or critical hazards.

Respiratory

No known significant effects or critical hazards.

Germ Cell Mutagenicity

Not available.

Conclusion/Summary

No known significant effects or critical hazards.

Carcinogenicity

Not available.

Conclusion/Summary

No known significant effects or critical hazards.

Reproductive toxicity

Not available.

Conclusion/Summary

No known significant effects or critical hazards.

Teratogenicity

Not available.

Conclusion/Summary

No known significant effects or critical hazards.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on likely routes of exposure : Not available.

Potential acute health effects

Eye contact : May cause eye irritation upon direct contact with eyes.

Inhalation : No known significant effects or critical hazards.

Skin contact : No known significant effects or critical hazards.

Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : No specific data.

Inhalation : No specific data.

Skin contact : No specific data.

Ingestion : No specific data.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Short term exposure

Potential immediate effects : Not available.

Potential delayed effects : Not available.

11. Toxicological information

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Potential chronic health effects

Not available.

Conclusion/Summary : No known significant effects or critical hazards.

General : No known significant effects or critical hazards.

Carcinogenicity : No known significant effects or critical hazards.

Germ Cell Mutagenicity : No known significant effects or critical hazards.

Teratogenicity : No known significant effects or critical hazards.

Developmental effects : No known significant effects or critical hazards.

Developmental effects : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Route	ATE value
Oral	11444.3 mg/kg

12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
Glycerol	Acute LC50 10000 mg/l Fresh water Acute LC50 5000 mg/l Fresh water	Daphnia Fish	24 hours 24 hours

Persistence and degradability

Product/ingredient name	Test	Result	Dose	Inoculum
Glycerol	OECD 301D Ready Biodegradability - Closed Bottle Test	92 % - 30 days	-	-

Product/ingredient name	Aquatic half-life	Photolysis	Biodegradability
Glycerol	-	-	Readily

Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
Glycerol	-1.76	-	low

Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.

Other adverse effects : No known significant effects or critical hazards.

13. Disposal considerations

Disposal methods

The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

14. Transport information

	ADG	ADR/RID	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-	-
Transport hazard class(es)	-	-	-	-
Packing group	-	-	-	-
Environmental hazards	No.	No.	No.	No.

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according to IMO instruments : Not available.

15. Regulatory information

Standard for the Uniform Scheduling of Medicines and Poisons

Schedule 2 PHARMACY MEDICINE

Australian Inventory of Industrial Chemicals (AIIC)

All components are listed or exempted.

New Zealand Inventory of Chemicals (NZIoC)

All components are listed or exempted.

HSNO Group Standard

Medicinal product

HSNO Approval Number

Not applicable

Approved Handler Requirement

Not applicable.

Tracking Requirement

Not applicable.

16. Other information

Key to abbreviations : ADG = Australian Dangerous Goods
 ADR = The European Agreement concerning the International Carriage of Dangerous Goods by Road
 RID = The Regulations concerning the International Carriage of Dangerous Goods by Rail
 IATA = International Air Transport Association
 IMDG = International Maritime Dangerous Goods
 GHS = Globally Harmonized System of Classification and Labelling of Chemicals
 IBC = Intermediate Bulk Container
 SUSMP = Standard Uniform Schedule of Medicine and Poisons
 UN = United Nations
 SWA = Safe Work Australia
 HSNO = Hazardous Substances and New Organisms Act 1996

Date of issue / Date of revision : 06/01/2023

Version : v1.0L
 (Version for updated GHS Revision 7 PSDS Template)

Procedure used to derive the classification

Classification	Justification
Not applicable	Medicinal product

References : Not available.

Indicates information that has changed from previously issued version.

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

Please read all labels carefully before using product.